

In response to the Examiner's request, copies of the references cited in the Information Disclosure Statement filed August 7, 1998 are provided herewith. Consideration of these references and initialing and return of the PTO-1449 form are respectfully requested

The Examiner has rejected all of the claims under 35 U.S.C. Section 103 (a) as being unpatentable over U.S. Patent 5,741,497 of Guerrero et al. in view of U.S. Patent 5,948,416 of Wagner et al. The Examiner contends that Guerrero et al. disclose methods for treating dermatologic disorders including chronoaging, wrinkles and environmental abuse with compositions comprising salicylate ester in aqueous form in amounts of 0.01 to 20%, preferably 0.1-10%, more preferably 1-8% and optimally 2-6% by weight (column 2, lines 10-58) and may also include ethyl alcohol and propylene glycol (column 3, line 2 and column 4, line 3). The Examiner acknowledges that Guerrero et al. only teach the use of derivatives of salicylic acid instead of the acid per se. However, the Examiner relies on Wagner et al. as teaching the equivalency of salicylic acid and derivatives thereof in cosmetic formulations (column 4, line 15 through column 6, line 40). The Examiner argues that it would have been obvious to one skilled in the art to use salicylic acid in the compositions of Guerrero et al. to treat the skin disorder, and that the expected result would have been cosmetically improved skin. This rejection is respectfully but strenuously traversed for the reasons set forth in detail below.

First of all, neither of the Guerrero et al. nor Wagner et al. patents is available per se as prior art against the presently claimed invention. Thus, Guerrero et al. and Wagner et al. have respective prior art dates of June 25, 1996 and May 8, 1996 under 35 U.S.C. Section 102 (e). Both of these dates are subsequent to applicants' effective filing date of February 8, 1996. Although Wagner et al. claim the benefit of two provisional patent applications having 1995 filing dates, applicants are unaware of the extent to which these applications support the disclosure of the '416 patent. A review of applicants' grandparent application no. 08/597,370, filed February 8, 1996 reveals that the present claims are substantially fully supported by that

application with the exception of the lower limit of 15 wt % salicylic acid in some of the presently pending claims, as compared to 20 wt % in application 08/597,370. Accordingly, the Examiner's rejection should be withdrawn for this reason alone.

Even assuming that Guerrero et al. and Wagner et al. somehow qualify as prior art against the presently claimed invention, the rejection is still improper. First of all, contrary to the Examiner's suggestion, Guerrero et al. does not teach the use of derivatives in general of salicylic acid, but only one specific class of salicylic acid esters, namely C<sub>11</sub>-C<sub>30</sub> alkyl or alkenyl esters of salicylic acid (see column 2, lines 30-40). Second, while Wagner et al. teach the use of salicylic acid and derivatives of salicylic acid, the derivatives contemplated by Wagner et al. are not esters, and certainly not C<sub>11</sub>-C<sub>30</sub> alkyl or alkenyl esters, but only other acid derivatives of salicylic acid (column 4, lines 18 and 48 and column 6, lines 8-10 and 22-23). Further, Guerrero et al. specifically teach against the use of salicylic acid and derivatives of salicylic acid which leave the acidic function free, due to the acidity and irritation caused by these acids and derivatives (see column 1, lines 49-54 and column 2, lines 1-3).

Therefore, not only is there no suggestion for combining the teachings of Guerrero et al. and Wagner et al., but Guerrero et al. specifically teach against the use of salicylic acid per se and acid derivatives of salicylic acid. Moreover, while the present inventors stated the belief that derivatives of salicylic acid, including esters thereof, may also exhibit similar functionality when used in the concentrated solutions of the present invention (see page 6, lines 4-9), it has been found in practice that derivatives which remove the acid functionality, including esters in which the acid functionality is neutralized, do not as a rule provide the desirable superficial chemical skin peels which are the basis of the skin treatments of the present invention. Accordingly, only the use of salicylic acid has been claimed in the present application, and only derivatives which retain the acid functionality are considered as possible equivalents.

Still further, neither Guerrero et al. nor Wagner et al. teach or suggest that their compositions effect a superficial chemical skin peel, as in the presently claimed invention, and it is unlikely due to the neutralized esters of Guerrero et al. and the other ingredients of Wagner et al. that such skins peels would be obtained. Accordingly, even if appropriate as references, the combination of Guerrero et al. with Wagner et al. is improper and still fails to teach the presently claimed invention. The rejection is therefore improper, and reconsideration and withdrawal are respectfully requested.

In the grandparent U.S. application no. 08/597,370 and during the International Preliminary Examination in International application PCT/US97/01919, the prior Examiner rejected claims 1-14 and 20-22 as obvious or lacking inventive step over the combination of Brody, "Chemical Peeling," Mosby Yearbook, Inc., St. Louis, MO, pages 53-73 (1992) in view of U.S. Patent 5,296,476 of Henderson. In response to the Written Opinion in the International application, applicants submitted a Declaration of one of the applicants Douglas E. Kligman, M.D., Ph.D., which reported experimental data from four of the Henderson hard corn remover formulations, which demonstrated the absence of any skin peeling or skin improvement with the Henderson formulations. A copy of the response to the Written Opinion from the International application, including the attached Declaration of Douglas E. Kligman, M.D., Ph.D. is enclosed for the Examiner's information. Also enclosed is a copy of the International Preliminary Examination Report of the Examiner mailed March 25, 1998. In the last paragraph of the International Preliminary Examination Report, the Examiner rejects the submitted Declaration as not having used the same solvent used by Henderson and as not showing all the ingredients used for the instant application. Accordingly, the claims were still held to lack inventive step.

However, it is submitted that the Examiner's position in the International Preliminary Examination Report was in error. Evidently, the Examiner did not carefully review the submitted Declaration, but thought that it was a previous declaration submitted in the

prosecution of application no. 08/597,370, in which different solvents were used. Thus, it is clear from the formulations set forth at page 3 of the enclosed Kligman Declaration that the exact solvents used in the hard corn remover at column 4, lines 21-25 of Henderson were also used in the formulations tested according to the Declaration. Moreover, these formulations were compared with three Kligman formulations at different concentrations which were representative of the compositions and methods of the presently claimed invention (see paragraph 8 of the Kligman Declaration). Hence, the enclosed Kligman Declaration accurately reproduces the Henderson formulations and presents comparative data with formulations which are representative of the presently claimed invention. Therefore, the Declaration is commensurate in scope with the claims and the Henderson reference.

Further, the enclosed Kligman Declaration presents reasons why the Brody reference is inapplicable to the presently claimed invention (see paragraphs 14 and 15 of the Declaration). Accordingly, any attempt to use the same rejection against the presently pending claims would be improper and should not be made in the present application. Thus, this is the best rejection which the prior Examiner could make from the previously cited prior art, and that rejection has been satisfactorily rebutted by the Response to Written Opinion in the International application and the accompanying Declaration of Douglas E. Kligman, M.D., Ph.D.

In view of the above remarks, it is submitted that all of the claims in the application patentably distinguish over all of the prior art of record and known to applicants, either alone or in combination. Accordingly, reconsideration and withdrawal of the rejection and an early notice of allowance are respectfully solicited. **In view of the long pendency of this application and its parent and grandparent applications, if the Examiner does not believe that the present response places the application in full condition for allowance, she is requested to telephone the undersigned before any further written action, so that a**

personal interview can be scheduled with the undersigned, the Examiner and at least one of the inventors to discuss the claimed invention and the prior art.

Respectfully submitted,

DOUGLAS E. KLIGMAN ET AL.

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(Date)

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Enclosures - prior art from IDS

Response to Written Opinion in PCT/US97/01919

International Preliminary Examination Report in PCT/US97/01919